

**AMENDMENTS TO THE CLAIMS**

This listing of claims will replace all prior versions and listings of claims in the application:

**Listing of Claims:**

Claims 1-22. (*Canceled*)

Claim 23. (*Currently Amended*) A medicated device comprising:

a scaffold substrate comprising adjacent edges or surfaces in close proximity to each other defining an opening; and

a coating ~~on said scaffold, said coating being on said surfaces and~~ bridging from one edge or surface to another across the opening, and said coating comprising at least one polymer and at least one therapeutic agent,

said therapeutic agent being at a loading of at least about 100 micrograms per square centimeter of coating.

Claim 24. (*Previously Presented*) The medicated device of claim 23, said therapeutic agent being at a loading of at least about 500 micrograms per square centimeter of coating.

Claim 25. (*Currently Amended*) The medicated device of claim 61, said coating comprising a bond coat layer and a layer comprising the therapeutic pharmaceutical agent.

Claim 26. (*Currently Amended*) The medicated device of claim 61, said substrate scaffold comprising a wire configured into a coil.

Claim 27. (*Currently Amended*) The medicated device of claim 26, said ~~scaffold comprising a wire configured into a coil~~ having open windings.

Claim 28. **(Currently Amended)** The medicated device of claim 61, said substrate scaffold selected from the group consisting of perforated wafers and wire meshes.

Claim 29. **(Currently Amended)** The medicated device of claim 61, said substrate scaffold selected from the group consisting of mandrels, beads, cylinders, egg-shaped articles, spheres, coiled articles, straight articles, threads, wires, pellets, tubing, and stents ~~configured to have adjacent edges or surfaces in close proximity to each other.~~

Claim 30. **(Previously Presented)** The medicated device of claim 61, wherein when said device is implanted in a tissue, a therapeutic amount of said therapeutic agent diffuses at least about one centimeter from said device.

Claim 31. **(Previously Presented)** The medicated device of claim 61, wherein in a zone of inhibition test, effective amounts of the therapeutic agent diffuse at least about one half centimeter from said device.

Claim 32. **(Previously Presented)** The medicated device of claim 61, said therapeutic agent being one or more selected from the group consisting of an antibiotic agent, an anticancer agent, an antiangiogenic agent, an antimicrobial agent, an antiviral agent, and an antithrombogenic agent.

Claim 33. **(Previously Presented)** The medicated device of claim 61, said therapeutic agent being one or more selected from the group consisting of docetaxel, fluorouracil, doxorubicin, cisplatin, mitomycin, peplomycin, merbarone, minocycline, penicillins, cephalosporins, fluoroquinolones, tetracyclines, Chloramphenicol, Polymixin B sulfate, Bacitracin zinc, aminoglycosides, clindamycin, lincomycin, thymol, silver compounds, benzethonium chloride, stearalkonium chloride, 1,2-benzisothiazolin-3-one, triclosan, polyhexa-methylene biguanide hydrochloride, heparin sodium, heparin complexed with a quaternary ammonium compound, heparin

complexed with benzalkonium chloride, heparin complexed with stearylalkonium chloride, heparin complexed with tridodecylmethylammonium chloride, hirudin, sugars, and aspirin.

Claim 34. *(Currently Amended)* The medicated device of claim 61, said therapeutic agent being one or more selected from the group consisting of rifamycin, gentamicin laurylsulfate, polyhexa-methylene biguanide hydrochloride, benzalkonium chloride, 2-bromo-2-nitropropane-1,3-diol, silver nitrate, and methotrexate, ~~and paclitaxel~~.

Claim 35. *(Previously Presented)* The medicated device of claim 61, said therapeutic agent comprising heparin and at least one additional agent.

Claim 36. *(Previously Presented)* The medicated device of claim 61, said coating comprising at least one hydrophobic polymer and at least one hydrophilic polymer.

Claim 37. *(Currently Amended)* The medicated device of claim 61, said coating comprising a first polymer and a second polymer, said first polymer being more hydrophilic than said second polymer.

Claim 38. *(Previously Presented)* The medicated device of claim 36, said hydrophilic polymer comprising a polymer being one or more selected from the group consisting of a polyacrylamide/ethylene glycol copolymer, a polyacrylamide/polyethylene oxide copolymer, polyvinylpyrrolidone, polyvinylpyrrolidone vinylacetate copolymer, a polyethylene glycol, and a polyethylene oxide.

Claim 39. *(Previously Presented)* The medicated device of claim 36, said hydrophobic polymer comprising an acrylate/carboxyl copolymer, a cellulose ester polymer, cellulose nitrate, a polyurethane polymer, an acrylate polymer, and an acrylate copolymer.

Claim 40. *(Previously Presented)* The medicated device of claim 36, said coating comprising at least as much hydrophobic polymer as hydrophilic polymer by weight.

Claim 41. *(Previously Presented)* The medicated device of claim 36, said coating comprising hydrophobic polymer and hydrophilic polymer in a weight ratio in the range of from about 1.5:1 to about 7:1.

Claim 42. *(Previously Presented)* The medicated device of claim 61, said coating comprising an acrylate polymer and polyvinylpyrrolidone/vinyl acetate copolymer in a weight ratio in the range of from about 1.5:1 to about 7:1.

Claim 43. *(Currently Amended)* A method for making a medicated device, comprising the steps of:

providing a substrate scaffold comprising edges or surfaces in close proximity to each other defining an opening;

providing a coating material comprising at least one polymer and at least one therapeutic agent; and,

applying the coating material to said scaffold to produce a coating ~~on said surfaces of said scaffold~~ and bridging from one edge or surface to another across the opening, the therapeutic agent being at a loading of at least about 5 micrograms per square centimeter of coating material.

Claim 44. *(Currently Amended)* The method of claim 43, comprising applying a polymeric coating sheath to said scaffold, and applying to said sheath a ~~coating layer of~~ said coating material comprising said polymer and said therapeutic agent.

Claim 45. *(Currently Amended)* A method of providing a therapeutic agent to a target tissue, comprising the steps of:

providing a medicated device comprising a substrate scaffold comprising adjacent edges or surfaces in close proximity to each other defining an opening, a coating ~~on said scaffold, said coating being on said surfaces and~~ bridging from one edge or surface to another across the opening, and said coating containing at least one polymer and at least one therapeutic agent and comprising one or more layers; and,

inserting the medicated device into the target tissue to provide therapeutic benefit, wherein a therapeutic amount of said therapeutic agent diffuses into the tissue at least about one centimeter from said device.

Claim 46. *(Previously Presented)* The method of claim 45, the tissue comprising a tumor or a lesion.

Claim 47. *(Previously Presented)* The method of claim 45, said inserting comprising inserting the medicated device into a tumor, wherein said therapeutic agent comprises an anti-cancer drug.

Claim 48. *(Previously Presented)* The method of claim 45, said inserting comprising inserting the medicated device into a lesion, wherein said therapeutic agent comprises an antibiotic.

Claim 49. *(Previously Presented)* The method of claim 45, further comprising inserting the medicated device using a trochar or catheter.

Claim 50. *(Currently Amended)* A medicated device comprising:  
a substrate suitable for implantation into a patient's body and comprising adjacent edges or surfaces in close proximity to each other defining an opening; and  
a formulation comprising at least one polymer and at least one therapeutic agent, the formulation bridging from one edge or surface to another across the opening, the therapeutic agent being at a loading sufficient to deliver a therapeutically effective quantity of the therapeutic agent when implanted in the patient's body.

Claim 51. *(Previously Presented)* The device of claim 50 wherein the substrate has an open, perforated, or mesh structure providing support for the formulation.

Claim 52. *(Previously Presented)* The device of claim 50 wherein the substrate is a stent.

Claim 53. ***(Previously Presented)*** The device of claim 50 wherein the therapeutic agent comprises paclitaxel.

Claim 54. ***(Previously Presented)*** The device of claim 50 wherein the substrate is a stent and the therapeutic agent comprises paclitaxel.

Claim 55. ***(Previously Presented)*** The device of claim 54 wherein the stent elutes about 10% of the paclitaxel over about 14 days.

Claim 56. ***(Currently Amended)*** The medicated device of claim 23, said substrate scaffold having a shape selected from the group consisting of mandrels, beads, egg-shapes, spheres, and threads ~~configured to have adjacent edges or surfaces in close proximity to each other.~~

Claim 57. ***(Previously Presented)*** The medicated device of claim 23, said therapeutic agent being an antiangiogenic agent.

Claim 58. ***(Previously Presented)*** The medicated device of claim 23, said therapeutic agent being an antiviral agent.

Claim 59. ***(Previously Presented)*** The medicated device of claim 23, said therapeutic agent being one or more selected from the group consisting of docetaxel, doxorubicin, mitomycin, peplomycin, minocycline, penicillins, cephalosporins, fluoroquinolones, tetracyclines, Chloramphenicol, Polymixin B sulfate, Bacitracin zinc, clindamycin, lincomycin, 1,2-benzisothiazolin-3-one, triclosan, polyhexa-methylene biguanide hydrochloride, hirudin, and aspirin.

Claim 60. ***(Previously Presented)*** The medicated device of claim 23, said therapeutic agent being one or more selected from the group consisting of polyhexa-methylene biguanide hydrochloride and 2-bromo-2-nitropropane-1,3-diol.

Claim 61. **(Currently Amended)** A medicated device comprising:  
a ~~scaffold~~ substrate comprising adjacent edges or surfaces in close proximity to each other defining an opening; and  
a coating ~~on said scaffold, said coating being on said surfaces and~~ bridging from one edge or surface of the substrate to another across the opening, and said coating comprising at least one polymer and ~~an effective amount of~~ at least one therapeutic agent at a loading sufficient to deliver a therapeutically effective quantity of the therapeutic agent when implanted in a patient's body.

Claim 62. **(Previously Presented)** The medicated device of claim 61, wherein the therapeutic agent comprises an antithrombogenic and/or an antiangiogenic agent in an effective amount.

Claim 63. **(Previously Presented)** The medicated device of claim 61, wherein said coating comprises at least one antithrombogenic agent.

Claim 64. **(Previously Presented)** The medicated device of claim 61, wherein said coating comprises at least one antiangiogenic agent.

Claim 65. **(Currently Amended)** The medicated device of claim 61, wherein said ~~scaffold~~ substrate comprises metal.

Claim 66. **(Previously Presented)** The medicated device of claim 61, wherein said coating comprises paclitaxel.

Claim 67. **(Currently Amended)** The medicated device of claim 65, wherein said ~~scaffold~~ substrate is a stent.

Claim 68. **(Canceled)**

Claim 69. *(Previously Presented)* The method of claim 43, wherein said therapeutic agent is in the coating at a loading of at least about 100 micrograms per square centimeter of coating.

Claim 70. *(Previously Presented)* The method of claim 45, wherein said therapeutic agent is at a loading of at least about 100 micrograms per square centimeter of coating.

Claim 71. *(Currently Amended)* The medicated device ~~method~~ of claim 50, wherein said therapeutic agent is at a loading of at least about 100 micrograms per square centimeter of the coating device.

Claim 72. *(Previously Presented)* The medicated device of claim 23, said therapeutic agent comprising paclitaxel.

Claim 73. *(Previously Presented)* The medicated device of claim 61, said therapeutic agent comprising paclitaxel.

Claim 74. *(Previously Presented)* The medicated device of claim 61, said therapeutic agent selected from the group consisting of heparin sodium and heparin complexed with a quaternary ammonium compound.

Claim 75. *(New)* The medicated device of claim 61, wherein the at least one polymer comprises a poly(L-lactic acid) blend.

Claim 76. *(New)* The medicated device of claim 61, wherein the at least one polymer comprises a polyester.

Claim 77. *(New)* A medicated device, comprising:  
a therapeutic agent;  
means for containing the therapeutic agent; and  
means for providing structural support to the containing means, wherein the



containing means bridges from one portion of the structural support providing means to another portion of the structural support providing means, wherein the therapeutic agent is at a loading sufficient to deliver a therapeutically effective quantity of the therapeutic agent in a patient's body when the device is implanted therein.

Claim 78. *(New)* The medicated device of claim 77, wherein the structural support providing means is selected from the group consisting of a perforated wafer, a wire mesh, and a stent.

Claim 79. *(New)* The medicated device of claim 77, wherein the therapeutic agent comprises paclitaxel.

Claim 80. *(New)* The medicated device of claim 77, the therapeutic agent being at a loading of at least about 5 micrograms per square centimeter of the containing means.

Claim 81. *(New)* The medicated device of claim 77, the therapeutic agent being at a loading of at least about 50 micrograms per square centimeter of the containing means.

Claim 82. *(New)* The medicated device of claim 77, the therapeutic agent being at a loading of at least about 100 micrograms per square centimeter of the containing means.

Claim 83. *(New)* The medicated device of claim 77, the therapeutic agent being at a loading of at least about 500 micrograms per square centimeter of the containing means.